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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/706,128	11/03/2000	Xiaoling Xie	VP198-04 CON	7839
Fish & Neave 1251 Avenue of the Americas New York, NY 10020			EXAMINER BORIN, MICHAEL L	
			ART UNIT 1631	PAPER NUMBER
			MAIL DATE 05/23/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

09/706,128

**Applicant(s)**

XIE ET AL.

**Examiner**

Michael Borin

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 16,17 and 19-26 is/are pending in the application.
- 4a) Of the above claim(s) 16,17 and 19-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### **Status of Claims**

1. Response and amendment filed 03/02/2007 are acknowledged. Claims 16,17,19-26 are pending.

In the previous Office action, claims 16,17,19-22 were withdrawn from consideration as being directed to a non-elected invention, and claims 23-26 were addressed. Applicant argues that claims have to be rejoined because their search would not be burdensome as a search of designing inhibitors "would likely" turn up references involving identifying inhibitors and vice versa. Examiner disagrees. As the term "would likely" used by applicant correctly suggests, a search of designing inhibitors may or may not turn up references involving identifying inhibitors and vice versa; thus the searches are not co-extensive. Claims 16,17,19-22 remain to be withdrawn from consideration as being directed to a non-elected invention, and claims 23-26 are being addressed.

2. Applicant's arguments filed have been fully considered and they are deemed to be persuasive-in-part. Rejections under 35 U.S.C.112, first and second paragraph is withdrawn in view of amendments to the claims and applicant's arguments.

***Claim Rejections - 35 USC § 103.***

Claims 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. (US 6,943,000; effective filing date 10/03/1997) .

The claims are directed to method for identifying JNK3 $\alpha$  inhibitor by generating three-dimensional structure containing coordinates of 25 amino acid residues (extended set of 45 residues is in claims 24,26), and using said structure to identify the inhibitor. Claim 25 also requires the step of producing a crystal of unphosphorylated JNK3  $\alpha$ .

Davis et al is directed to methods of identification and use of JNK3 modulators. The reference teaches that computer modeling is used to identify compounds that modulate activity of a JNK3 protein by reacting, for example with its active site. The active site of JNK3 can be identified using methods known in the art including, for example, X-ray crystallographic methods. Having determined the 3D structure of the active site of a JNK3 protein, candidate modulating compounds can be identified; the compounds identified in such search are those that have structures that match the active site structure, fit into the active site, or interact with groups defining the active site.

X-ray crystallographic methods can be used to identify the active site of JNK3 by the location of a bound ligand such as c-Jun or ATF2. The three-dimensional structure of the active site can be determined. This can be done using known methods, including X-ray crystallography, which can be used to determine a complete molecular structure... Geometric structure can be determined with a JNK3 protein bound to a natural (e.g., c-Jun or ATF2) or artificial ligand which may provide a more accurate active site structure determination”

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Computer-based numerical modeling can be used to complete an incomplete or insufficiently accurate structure. Modeling methods can be used... Having determined the structure of the active site of a JNK3 protein, either experimentally, by modeling, or by a combination of methods, candidate modulating compounds can be identified by searching databases containing compounds along with information on their molecular structure. The compounds identified in such a search are those that have structures that match the active site structure, fit into the active site, or interact with groups defining the active site. The compounds identified by the search are potential JNK3 modulating compounds.

See col. 7. Further, the activity of thus identified ligands is tested. See col. 9. The method of Davis et al is applicable to any of known JNK3 proteins (see col. 3, bottom) or fragments thereof. In particular, JNK3 proteins of SEQ ID No. 5,8, comprise residues as instantly claimed. JNK3 protein of SEQ ID No. 10 is a JNK3 fragment truncated at N-terminal.

Even though the method disclosed by Davis et al. does not specify the atomic coordinates of JNK3 $\alpha$  according to Figure 1A, Davis addresses JNK3 proteins having the same sequence; further, the specific limitations of atomic coordinates in this instant case do not distinguish the invention from the prior art in term of patentability because they are descriptive nonfunctional subject matter.

The following excerpt is from M.P.E.P. 2106 Section VI :

If the difference between the prior art and the claimed invention is limited to descriptive material stored on or employed by a machine, Office personnel must determine whether the descriptive material is functional descriptive material or nonfunctional descriptive material, as described supra in paragraphs IV.B.1(a) and IV. B.1(b).

Nonfunctional descriptive material cannot render nonobvious an invention that would have otherwise been obvious. In re Ngai, F.3d, 2004 WL 1068957 (Fed. Cir. May 13, 2004).< Cf. In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983)

Common situation involving nonfunctional descriptive material is a process that differs from the prior art only with respect to nonfunctional descriptive material that cannot alter how the process steps are to be performed to achieve the utility of the invention.

Specific to the instant case, atomic coordinates in Figure 1A are merely stored so as to be read or outputted by a computer without creating any functional

interrelationship, either as part of the stored data or as part of the computing processes performed by the computer, then such descriptive material alone does not impart functionality either to the data as so structured, or to the computer.

Response to arguments

Applicant argues, p. 23 of the response, that, first, Davis does not teach using unphosphorylated JNK3 protein, and, second, requires use of the entire JNK3 $\alpha$  protein rather than a specific set of amino acid coordinates. However, in the cited above discussion of using 3-D coordinates of active site of JNK3 protein to identify inhibitor, Davis is silent about the phosphorylation status of the protein, and there is no reason to believe that the reference requires phosphorylated JNK3 $\alpha$  as asserted by applicant. In fact, the only occurrence of explicit mention of phosphorylated JNK3 protein appears in discussion of use of antibodies in immunological testing (Example 10).

With respect to the second argument that the reference requires use of the entire JNK3 $\alpha$  protein rather than a specific set of amino acid coordinates, using coordinates of residues of the entire protein would thus include use of residues recited in the claims - note that JNK3 proteins of Davis comprise the same residues as instantly addressed; see SEQ ID No. 5,8,10. In addition, Davis suggest using coordinates of residues comprising an active site.

With respect to coordinates listed in Figure 1, Examiner maintains that a list of coordinates represents non-functional descriptive material, and such descriptive material alone does not impart functionality either to the data as so structured, or to the computer.

***Conclusion.***

No claims are allowed

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571)272-0735 . The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Michael Borin, Ph.D.  
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Art Unit 1631

mlb